



STATE OF TENNESSEE
DEPARTMENT OF ENVIRONMENT AND CONSERVATION

DIVISION OF RADIOLOGICAL HEALTH

L & C Annex, 3rd Floor

401 Church Street

Nashville, TN 37243-1532

Phone: 615-532-0360, Fax: 615-532-7938, E-mail: Eddie.Nanney@tn.gov

April 16, 2010

Honorable Edward J. Markey
Chairman, Subcommittee on Energy and Environment
Committee on Energy and Commerce
U. S. House of Representatives
Congress of the United States
2125 Rayburn House Office Building
Washington, D.C. 20515-6115

Dear Chairman Markey:

Enclosed are the answers from the State of Tennessee to the questions submitted with your letter dated March 18, 2010, concerning the release of patients treated with medical radioisotopes.

1. How many I-131 licensee facilities are overseen by your State?

Eighty-seven (87) licensee facilities are authorized for Iodine 131 (I-131) for medical therapy.

2. How often does your State perform sampling inspections each of these I-131 licensee facilities?

Tennessee inspects medical licensees that administer therapeutic doses of I-131 at least every three years. Inspection frequencies are based upon the type and scope of the program, and are sometimes more frequent than those of the U. S. Nuclear Regulatory Commission (NRC). We have two Broad Scope Medical licensees that are inspected every two years. The medical licensees that administer therapeutic doses of I-131, which are referred to as Medical Institution – Written Directive Required, are inspected at a frequency of once every three years.

3. What does such an inspection entail? Please provide copies of any handbooks or inspection checklists or other similar documents that are used to conduct such inspections.

Tennessee follows applicable NRC guidance such as Inspection Manual Chapter 2800 (IMC 2800), including the inspection criteria for a facility requiring written directives, and including those facilities that administer I-131, in Inspection Procedure (IP) 87131, Nuclear Medicine Programs, Written Directive Required. Regarding the release of patients, inspectors determine, by direct observations and, if needed, by review of selected records, that the licensee is knowledgeable regarding patient release criteria and is in compliance with the patient release criteria identified in the license.

4. **NCRP 155 includes "Radiation Safety Precautions for Radiopharmaceutical Therapy Patients." For a patient receiving 175 millicuries of I-131, the patient is instructed not to hold or embrace children for more than 10 minutes a day for 21 days; to refrain from sharing a bed with one's sleeping partner for 7 days; and for the first day, to store and launder one's used clothing and bed linens separately from the rest of the household, using two rinse cycles; to wipe down the telephone with paper towels and then discard the paper towels; etc. What instructions has your State given to its medical licensees about how to provide guidance to patients to ensure that these radiation precautions will be followed?**

Medical licensees in Tennessee have been provided the guidance contained in NUREG-1556, Vol. 9, Appendix U, Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials. They are requested to commit to this guidance, which then becomes a requirement of their license. This guidance requires that instructions concerning precautions for released patients be provided for certain levels of treatment. Licensees may develop their own instructions. We do not provide explicit instructions to medical licensees. We have also referred licensees authorized for medical use of therapeutic amounts of I-131 to NRC Regulatory Issue Summary 2008-11, Precautions To Protect Children Who May Come In Contact With Patients Released After Therapeutic Administration of Iodine 131.

5. **In the past ten years, how many times has your State, as part of the inspections it conducts, requested documentation from the licensee facilities that details the individualized analysis and/or dose calculations used when determining whether to send a patient that was treated with I-131 in excess of the default limits home, or to a hotel?**

During the inspection of medical facilities using quantities of I-131 that require a determination regarding patient release, our inspectors evaluate the licensee's program to verify compliance with Tennessee requirements. This evaluation includes a determination of whether the licensee is knowledgeable regarding patient release criteria and whether appropriate records to document the basis for authorizing patient releases are maintained. These records are reviewed at the licensee's facility during the inspection. Documentation including individualized analysis and/or dose calculations may be reviewed. Neither

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detailed records of these reviews, due to patient privacy concerns, nor any record of how many times inspectors have reviewed such records, are kept.

- 6. In the past ten years, how many times has your State, as part of these inspections, requested documentation from the licensee facilities that details the guidance provided to the patient by the licensee facility when the patient is released from licensee care?**

Tennessee does not require licensees to maintain copies of the instructions provided to individual patients. During inspections, the inspector reviews a random sampling of cases for compliance. If the licensee does not keep copies of instructions for each patient, or if appropriate instruction examples are not available, the inspector determines the licensee's compliance with Tennessee requirements by evaluating whether the licensee is knowledgeable regarding patient release criteria and skilled in communicating instructions to patients. Tennessee does not keep a specific record of how many times inspectors have reviewed patient-specific guidance documents.

- 7. In the past ten years, how many times has your State identified problems with the individualized analysis and/or dose calculations used or guidance provided to the patient by the licensee facility? Please detail these problems.**

In the past 10 years, Tennessee has not identified any problems with the individualized analysis and/or dose calculations used or guidance provided to the patient by the licensee.

- 8. In situations where an individualized analysis of dose to others is required, it would seem impossible for the authorizing physician to do so for a patient going to a hotel, since this would require a knowledge of the layout of the hotel and the proximity to the nearest other guest, who might be a child or a pregnant woman sleeping on the other side of a wall. Do you agree?**

Tennessee believes that licensees are capable of calculating conservative dose estimates using reasonable assumptions concerning occupancy, building geometry, and other factors.

- 9. Has your State ever attempted to determine how many patients treated with I-131 are a) sent home, b) sent to a hotel or c) kept in the hospital for additional time? If so, please provide the results. If not, why not?**

Tennessee has not. There is no regulatory basis for collecting such information. During inspections at medical facilities, inspectors review a random sampling of cases involving therapeutic uses of radioactive materials to determine from patient records the circumstances surrounding which the patient was released, and the content of the counseling the patient received. These reviews are used to verify compliance with the Tennessee requirements, regardless of the patient's final destination.

- 10. In patients with doses in excess of the default limits, has your State ever attempted to determine whether these I-131 licensee facilities always perform individualized analysis of each patient's living circumstances prior to releasing them? If not, why not? If so, has your State ever encountered situations when individual analyses and/or dose calculations were not performed when they were required? Please provide reports and documentation relating to these cases.**

Tennessee inspectors evaluate the licensee's program for patient release to verify compliance with Tennessee requirements. Included in this evaluation is a review of the licensee's process for performing individualized analysis, including patient-specific calculations. We have not identified any situations in which adequate dose calculations were not performed.

- 11. What are the disclosure rules for patients who go to a hotel following treatment? Are licensees required to give patients explicit instructions to provide to hotel management?**

Tennessee utilizes NRC guidance to medical use licensees, which provides general objectives rather than prescriptive directions. NRC requires the instructions to include actions the licensee recommends that meet the general objective of maintaining doses to other individuals as low as reasonably achievable, but licensees are not required to give patients explicit instructions to provide to hotel management.

- 12. Has your State ever issued an advisory or guidance warning licensees not to send radioactive patients to hotels? If so, please provide copies.**

Tennessee has not.

- 13. Are your licensees required to report to you instances in which released I-131 patients caused radiation exposure to family members or members of the public?**

Tennessee does not require such a report.

- 14. Please provide copies of all correspondence including emails, letters, meeting or telephone notes or other materials between your State and the NRC related to the release of patients treated with radio-nuclides.**

There are none specifically relating to the subject of this request.

- 15. Please also provide reports for instances in which documents relating to patient release were found to be missing, inadequate, or unclear during the course of a sampling inspection. If your sampling inspections found that a licensee knew of a patient who went to a hotel after treatment, whether or not by explicit instruction, please provide all documentation relating to those cases.**

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If required patient release documentation is missing or inadequate, it is considered a violation of Tennessee requirements and would be cited as such by an inspector. If the documentation is unclear, the inspector will ask additional questions to determine whether or not a violation has occurred. The determination regarding compliance is reflected in the inspection report. There are no known cases where patients went to a hotel in Tennessee.

If you have additional questions or concerns, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink, reading "Lawrence E. Nanney". The signature is written in a cursive style with a large, stylized "L" and "N".

Lawrence E. Nanney
Director